K051971

AUG 4 - 2005

510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information:

Contact: Betty Lim
Regulatory Affairs

Sponsor: U&i Corporation
YongHyun-Dong 529-1, Euijungbu
Kyonggi-Do, Korea 480-050
Phone: 82-31- 852-0102(ext. 254)
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Date Prepared: July 18, 2005

Device Identification

Trade Name: *OPTIMA™* Spinal System

Common Name: Rod, hook, and screw spinal instrumentation

Classification Name: Spinal Pedical Fixation Orthosis (MNI) per 21 CFR § 888.3070

Spondylolisthesis Spinal Fixation Orthosis (MNH) per 21 CFR § 888.3070

Spinal Intervertebral Body Fixation Orthosis (KWQ) per 21 CFR § 888.3060

Substantially Equivalent Predicate Legally Marketed Devices

The subject *OPTIMA™* Spinal System is substantially equivalent in intended use, operating principle, materials, shelf life, packaging materials and process to:

K051971

Device Description

The *OPTIMA*™ Spinal System is a top-loading multiple component, anterior / posterior spinal fixation system which consists of pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism.

The *OPTIMA*™ Spinal System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The *OPTIMA*™ implant system components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available. Specialized instruments made from surgical grade stainless steel are available for the application and removal of the *OPTIMA*™ system

Indications for Use:

The *OPTIMA*™ posterior spinal fixation device is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the *OPTIMA*™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

When used as an anterior screw fixation system, the *OPTIMA*™ is indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, Spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

Statement of Technological Comparison:

Mechanical testing was carried out according to ASTM F1717-01 & ASTM F1798-97 to validate the *OPTIMA*™ Spinal System. The testing demonstrated substantially equivalent to the *OPTIMA*™, Spinal System in terms of intended use, operating principle, materials, shelf life, packaging materials and process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Ms. Betty Lim
Regulatory Affairs
U and I Corporation
Youghyun Dong 529 1
Uijungbu, Kyunggi Do 480-050
Korea

Re: K051971
Trade/Device Name: OPTIMA™ Spinal System
Regulation Number: 21 CFR 888.3060, 21 CFR 888.3070
Regulation Name: Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWQ, MNH, MNI,
Dated: July 20, 2005
Received: July 21, 2005

Dear Ms. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

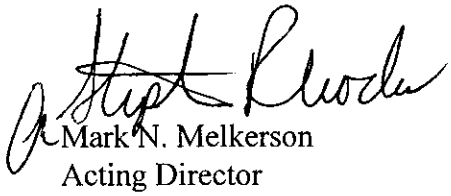
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS for USE STATEMENT

510(k) Number (if known): K051971

Device Name: *OPTIMA™* Spinal System.

Indications for Use: The *OPTIMA™* posterior spinal fixation device is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use X **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Ludwick

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051971